IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: GREFF, et al.

Title: Compositions For Use in Embolizing Blood Vessels

Patent No.: 5,667,767

Issue Date: September 16, 1997

Art Unit: 1511

Communication in Response to Correspondence from Department of Health & Human Services dated March 13, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants have reviewed the March 13, 2007 correspondence from Ms. Jane A. Axelrad of the Department of Health & Human Services.

After review of the correspondence and the relevant papers, Applicants concur that the total length of the regulatory review period for ONYX LES is **1,682 days**. Applicants originally stated in the Application for Extension of Patent Term under 35 U.S.C. § 156 filed on September 14, 2005 (hereinafter the "Application") that the regulatory review period for ONYX LES was **1,680 days**. This miscalculation was inadvertent. The undersigned apologizes for any inconvenience this may have caused.

Applicants also concur that the date of the premarket approval application (PMA) ONYX LES (PMA P030004) was submitted on March 18, 2003. Applicants originally stated in the Application that the premarket approval application (PMA) ONYX LES (PMA P030004) was submitted on March 12, 2003. This error was also inadvertent. Again, the undersigned apologizes for any inconvenience this may have caused.

In light of the above, Applicants submit the following statements in furtherance of the Application:

1. Relevant Dates – Please see page 7 of the Application.

The relevant dates and information pursuant to 35 U.S.C. § 156(g) are as follows:

(A) December 14, 2000 – Effective date of IDE G000296.

(B) March 18, 2003 – PMA P030004 submitted to FDA.

(C) July 21, 2005 – PMA P030004 approved by FDA.

2. Statement as to the Length of Extension Claimed – Please see page 10 – 13 of the Application.

The term of U.S. Patent 5,667,767 should be extended by **1,270 days**, or until **January 17, 2019** (including the additional day due to leap year).

As set forth in 35 U.S.C. § 156 (g)(3)(B), the regulatory review period equals the sum of the following periods (i) and (ii):

> (i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
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> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

The regulatory review period started on December 14, 2000, the day that IDE G000296 became effective. An application was initially submitted with respect to the device under section 515 on March 18, 2003. The number of days from December 14, 2000 to March 18, 2003 was 825 days. The application was approved under such Act was July 21, 2005. The number of days from March 18, 2003 to July 21, 2005 was 857 days (including the additional day

due to the leap year). Thus, the regulatory review period was **1,682 days** (including the additional day due to the leap year).

In accordance with 35 U.S.C. § 156(c), the term of a patent eligible for extension shall be extended by the time equal to the regulatory review period for the approved product which occurred after the date the patent issued. U.S. Patent 5,667,767 issued on September 16, 1997. The regulatory review period began on December 14, 2000. Thus, there were no days of regulatory review prior to the issuance of the patent.

Section 156 (c) also sets forth the following exceptions (1)-(3) which may operate to shorten the length of the review period used to calculate the patent term extension:

> (1) each period is reduced by any period during which the application did not act with due diligence.

In the opinion of the Applicant, there has been no lack of due diligence during the period of regulatory review calculated above. Accordingly, no reduction in the review period is required by this provision.

> (2) each period includes only one-half of the number of days in phase (i).

One-half the number of days in phase (i) equals one-half of 825 days (the number of days from December 14, 2000 to March 18, 2003) or 412 days (the half day being ignored). Subtracting this number from the regulatory review period (1682 days) results in a patent term extension of 1,270 days.

> (3) if the period remaining in the patent term after the date of approval of the approved product was added to the regulatory review period as revised under paragraphs (1) and (2) above exceeds fourteen years, the period of extension shall be reduced so that the sum of both periods does not exceed fourteen years.

On the date of approval of the product, 10 years and 6 days remained in the term of U.S. Patent 5,667,767. Adding this period to the review period calculated above yields a period of less than fourteen years. This provision, therefore, does not operate to shorten the period of extension to which U.S. Patent 5,667,767 is entitled.

Section 156(g)(6) limits the period of patent term extension to a maximum of five years from the original date of the patent. The original expiration date of U.S. Patent 5,667,767 is July 27, 2015. The maximum extension allowed by this provision would extend the term to July 27, 2020. Extension of the patent term by the number of days calculated above would not extend the patent beyond July 27, 2020. Accordingly, this provision does not limit the patent term extension available.

In sum, U.S. Patent 5,667,767 is entitled to an extension of patent term until January 17, 2019 or 1,270 days.

3. Conclusion

Applicant acknowledges the duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought.

The undersigned, a duly authorized agent of Micro Therapeutics, Inc., hereby declares:

(1). that she is a patent attorney authorized to practice before the United States Patent and Trademark Office and has general authority from Applicant for the purpose of transacting all matters reasonably related to obtaining an extension of patent term for U.S. Patent No. 5,667,767;

(2). that she has reviewed and understands the content of this application being submitted pursuant to 35 U.S.C. § 156;

(3). that she believes the patent is subject to extension pursuant to 37 C.F.R. § 1.710;

(4). that she believes an extension of the length claimed is justified under 35 U.S.C. § 156 and the applicable regulations; and

(5). that she believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. § 1.720.

Based on the above, Applicants request that the Office grant an extension of the patent term consistent with the statements made herein.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date May 1, 2007 By Lorna L. Tanner

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